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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,559	11/15/2001	Avi J. Ashkenazi	P2730P1C40	5102

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,559	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 18 June 2004 has been entered in full. Claims 119-131 are under examination.

The information disclosure statement (IDS) filed 18 June 2004 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The Declaration of Avi Ashkenazi under 37 CFR1.132 has been entered.

The Declaration of Paul Polakis under 37 CFR1.132 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claims 119-123, 130 and 131 under 35 U.S.C. 112, first paragraph, written description, as set forth at pages 7-9 of the previous Office Action (22 March 2004) is *withdrawn* in view of the amendment (18 June 2004).

The rejection to claims 119-131 under 35 U.S.C. 112, second paragraph, as set forth at pages 9-10 of the previous Office Action (22 March 2004) is *withdrawn* in view of the amendment (18 June 2004).

35 U.S.C. §§ 101 and 112, First Paragraph

Claims 119-131 remain rejected under 35 U.S.C. § 101 because the claimed invention is not supported by a specific and substantial asserted utility or a well established utility.

Claims 119-131 remain rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would clearly not know how to use the claimed invention.

The basis for these rejections is set forth at pages 2-7 of the previous Office Action (22 March 2004).

Applicant's arguments submitted in the response received 18 June 2004 have been fully considered but are not found to be persuasive for the following reasons. The Ashkenazi declaration and Polakis declaration under 37 CFR 1.132 filed 18 June 2004 is insufficient to overcome the rejection of claims 119-131 based upon 35 U.S.C. §§ 101 and 112, first paragraph, as set forth in the last Office action for the following reasons.

Applicant states that the Examiner acknowledged that the nucleic acids encoding PRO1187 showed a positive correlation for lung cancer. Applicant maintains that the claimed utility for the PRO1187 protein and its antibody is based on its use in the diagnosis of adenocarcinomas of the lung or colon and that Applicant relies on the gene amplification data for the patentable utility of this case. Applicant states that if the Applicant has asserted that the claimed

invention is useful for any particular practical purpose and the assertion would be considered credible by a person of ordinary skill in the art; do not impose a rejection based on the lack of utility. Applicant cites the Guidelines for Examination of Applications for Compliance with the Utility Requirement, set forth in MPEP 2107 II (B) in support of this assertion. Applicant urges that a *prima facie* case of lack of utility has not been established.

Applicant criticizes the Examiner's reliance on Haynes *et al.,* Pennica *et al.* and Konopka *et al.* (all of record). Applicant states that Haynes *et al.* teach that there was a general trend but no strong correlation between protein expression and transcript levels. Applicant states that the teachings of Pennica *et al.* are specific for WISP family genes and are not directed to genes in general. Applicant argues that Konopka does not disclose any generalized teaching about the correlation between protein expression and gene amplification and the reference is not sufficient to establish a *prima facie* showing of lack of utility based on the results of the abl gene alone. Applicant asserts that the working hypothesis among those skilled in the art is that, if a gene is amplified in cancer, the encoded protein is likely to be expressed at an elevated level. Applicant discusses the references submitted in the IDS to demonstrate that if a gene is amplified in cancer, it is more than likely than not that the encoded protein will be expressed at an elevated level.

Applicant's arguments have been carefully considered but are not found to be persuasive. Firstly, the Examiner stated, "while the specification **may have** utility for the polynucleotide, the instant claims are drawn to the polypeptide"

(previous Office Action 22 March 2004, page 4). The Examiner **did not** acknowledge that the nucleic acid encoding PRO1187 showed a positive correlation for lung and colon cancer. Secondly, the Examiner is not questioning whether the asserted utility is credible. The question is whether the asserted utility is specific or substantial. No evidence has been submitted that it is the norm rather than the exception that protein levels are increased when gene amplification occurs in cancer. The state of the art regarding gene amplification and increased protein levels can be opposing as indicated by the references cited by the Examiner and Applicant. Indeed, given the disclosure in art, such as Pennica *et al.*, Konopka *et al.*, and Haynes *et al.*, that there is not always such a correlation, the skilled artisan would not assume it is so, **but would perform the experiment to verify it** (Emphasis added). Therefore, the art indicates that it is not the norm that gene amplification, or even increased transcription, results in increased protein levels.

Applicant refers to the Polakis declaration, which asserts that in approximately 80% of their observations, they have found that increases in the level of a particular mRNA correlates with changes in the level of protein expressed from that mRNA. Applicant refers to the Ashkenazi declaration, which asserts that if the protein levels do not increase as a result of gene amplification, it is also useful because it can serve to better diagnose the cancer.

This has been fully considered but is not found to be sufficient to withdraw the rejection, since **there is no indication that the PRO1187 protein levels increase or stay the same** (Emphasis added). Further research would be

needed to determine PRO1187 protein levels in cancers showing gene amplification of PRO1187 gene. Therefore, the asserted utility is not substantial, as the real-world use has not been established. Thus, the proposed use of the PRO1187 proteins as claimed in this application are simply starting points for further research and investigation into potential practical uses of the proteins and antibodies. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), wherein the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Therefore, the rejections under 35 U.S.C. §§ 101 and 112, first paragraph, are maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

RMD
9/2/04

ELIZABETH KEMMERER
PRIMARY EXAMINER

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